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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/776,454 | 02/02/2001 | Gregorio del Val | 2001-0705 | 9327 |

7590

01/02/2002

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| EXAMINER |
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WHITEMAN, BRIAN A

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| ART UNIT | PAPER NUMBER |
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1633

DATE MAILED: 01/02/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/776,454

Applicant(s)

VAL ET AL.

Examiner

Brian Whiteman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Telephone interview on 12/12/01.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-21 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

A telephone call was made to Michael Ward on 12/12/01 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Claims 1-21 are pending in this application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1, 2, 5, 6, 7, 8, 9, 10, 11, and 12, drawn to a method for testing the allergenicity of a heterologous protein produced by a genetically modified plant, classifiable in class 424, subclass 9.1, class 800, subclass 4, subclass 13.
- II. Claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, and 12, drawn to a method for testing the allergenicity of a heterologous protein produced by a genetically modified animal, classifiable in class 424, subclass 9.1, class 800, subclass 4, subclass 13.
- III. Claims 13-21, drawn to a method for testing a biological substance for allergenicity in human; a dog useful for testing biological substance for allergenicity in humans, classifiable in class 800, subclass 8.

The inventions are distinct, each from the other because:

Inventions III and I, II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product

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as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, invention III is directed to a dog useful for testing a biological substance for allergenicity in humans. The product can be used in materially different processes, e.g. commercial purposes, selling and/or breeding of dogs. In addition, materially distinct products can be used in the claimed invention (e.g. rabbits, mice, or pigs). Furthermore, the product can be used in materially different processes as exemplified in Groups I and II, which are directed to testing allergenicity of a heterologous protein produced by a genetically modified plant or animal using the dog of Group III, respectively. Furthermore, the product reads on a dog that is exposed to allergens from humans without manually introducing the allergens to said dog (e.g. when a dog eats dog food or is in the presence of humans, it could be exposing itself to allergens from humans). In addition, in view of the different classifications of Groups I –III, the search for Group III would not overlap with the genetically modified plants or animals of Group I and II. Thus, Group III is distinct from Groups I and II.

Although there are no provisions under the section for “Relationship of Inventions” in MPEP 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because each of the methods of inventions I, II, and III, constitutes patentably distinct inventions for the following reasons: Each of the inventions is directed to different goals and comprises materially distinct steps, wherein each of the compositions in each invention is structurally distinct and/or generates distinct mechanisms and functional effects as indicated above, invention I uses genetically modified plants, invention II uses genetically modified animals, and invention III uses wild type substance (e.g. pollen, ragweed, etc.). Invention III does not encompass using genetically modified animals or plants to produce the allergens. The

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scope of each of the cited inventions encompasses an employed method, which generates distinct function(s) and effect(s), and furthermore does not necessarily overlap with that of another invention. Furthermore, invention I is directed to a method for testing the allergenicity of a heterologous protein produced by a genetically modified plant; invention II is directed to a method for testing the allergenicity of a heterologous protein produced by a genetically modified plant, and invention III is directed to a method for testing the allergenicity of a biological substance for allergenicity in humans. Inventions I, II, and III comprise materially distinct steps, and/or generates different functions and effects, and thus, is not required for use with one another. Therefore the invention of group I is distinct from groups II and III.

If applicants elect either Group I or Group II, claim 1 is generic to a plurality of disclosed patentably distinct species comprising different routes of administration comprising injecting, feeding, or applying the extract to the skin of the newborn dog. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

In addition, if applicants elect either Group I or Group II, claim 2 is generic to a plurality of disclosed patentably distinct species comprising several different challenging and observing steps. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

If applicants' elect Group III, claim 13 is generic to a plurality of disclosed patentably distinct species comprising different routes of administration comprising injecting or feeding the allergen, control material, and test substance to the dog. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed.

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II and III, restriction for examination purposes as indicated is proper.

It would be unduly burdensome for the examiner to search and consider patentability of all of the presently pending claims, a restriction for examination purposes as indicated is proper.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Tracey Johnson whose telephone number is (703) 305-2982. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

^{02 1/26/01} ^{mentor} supervisor, Dave Nguyen can be reached at (703) 305-2024.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-2742.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-8724.

Brian Whiteman

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BW



DAVE T. NGUYEN
PRIMARY EXAMINER